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THE EFFICACY OF A STANDARDIZED ROSE-HIP POWDER CONTAINING SEEDS AND SHELLS COMPARED WITH GLUCOSAMINE SULFATE IN PATIENTS WITH OSTEOARTHRITIS OF THE KNEE - A BLINDED, PARALLEL, RANDOMIZED STUDY

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Purpose: Knee osteoarthritis is a degenerative disease caused by imbalance between formation and the destruction of cartilage, having pain, and crepitating knee as the most prominent symptoms. Rose-hip powder (RHP) is a well-known herbal remedy in Northern Europe, and glucosamine sulfate (GS) is commonly used to relieve symptoms of knee osteoarthritis. The purpose of this study was to compare the efficacy of a standardized Rose-hip powder, manufactured by Hyben-Vital, Langeland, Denmark, to glucosamine sulfate, in a blinded, parallel, randomized, controlled study.
Methods: Patients with moderate to severe symptoms of knee osteoarthritis according to the criteria of the American College of Rheumatology, without infectious arthritis, and not taking either of the studied supplements for the last 6 weeks before entering the study, were randomly recruited. Primary endpoints were to measure the efficacy of each remedy, and to compare the efficacy of the two remedies, in the reduction of symptoms from knee osteoarthritis such as pain, stiffness and functional disability, measured by WOMAC score, at the end of 3rd, 5th and 8th week of treatment. The Secondary endpoints included the reduction of analgesic consumption and the incidence of adverse reactions at the end of the 8th week of treatment. Statistical evaluation: WOMAC score changes within group were analyzed by Repeated Measure two-ways ANOVA. Subanalysis of values between groups was done by t-test. Data are given as mean values ± SD. P value of less than 0.050 is regarded as statistical significant.
Results: A number of 46 patients, 24 patients, 3 males 21 females, mean age of 58.25±10.76 years, mean weight of 62.20±8.85, with mean WOMAC total score of 44.17±11.87, were included in the GS group and 22 patients, 1 male, 21 female, mean age of 60.41±10.00, mean weight of 61.99±10.56, with mean WOMAC total score of 44.51±13.17, were included in the RHP group. All completed the study. There was no significant difference in the subject characteristics between groups at the initial level. Glucosamine sulfate (GS) was given at the dose of 1500 mg per day, while Rose-hip powder (RHP) was given at 4500 mg per day. Results showed that, total WOMAC scores at the end of 3rd, 5th and 8th week in GS group declined with statistically significance from 44.17±11.87 to 33.92±10.88 ($p<0.001$), 24.83±12.16 ($p<0.001$), and 17.46±12.11 ($p<0.001$), respectively, while the RHP group also showed statistically significant decrease in total WOMAC score from 44.50±13.17 to 29.59±15.86 ($p<0.001$), 19.36±14.87 ($p<0.001$) and 9.54±13.59 ($p<0.001$) respectively. The total WOMAC scores of RHP group was significantly lower than GS group at the end of the 8th week ($p<0.044$). WOMAC scores on pain and stiffness also decreased significantly in both groups, without statistical significant difference between groups. The RHP group showed lower WOMAC score on functional disability, with statistical significance ($P<0.015$) when compared to GS group at the end of the 8th week. Both groups were able to reduce the use of analgesics at the end of 8th week, with no significant difference between groups. The GS group demonstrated more incidences of adverse reactions (27 incidences, 15 cases) than the RHP group (16 incidences, 10 cases).
Conclusions: In conclusion, both GS and RHP were able to significantly reduce symptoms of knee osteoarthritis, such as pain and stiffness, after 3 weeks of treatment. RHP showed better efficacy than GS in term of total WOMAC score reduction, and functional disability reduction at the end of the 8th week, with less evidence and severity of adverse reactions.

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NEW FORMULATION WITH POTENTIAL FOR THE PREVENTION AND TREATMENT OF OSTEOPOROSIS AND OSTEOARTHRITIS

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Purpose: Osteoarthritis (OA) is a multidimensional disease that affects all anatomical joint structures, particularly cartilage, synovium and subchondral bone. In turn, osteoporosis (OP) is a skeletal disorder characterized by a compromised bone strength which substantially increases the risk of fracture. Both are common disorders which affect quality of life in the elderly. Despite this, there is not any drug at the moment approved for the simultaneous prevention and treatment of osteoporosis and osteoarthritis.
The aim of this study was to investigate the effect of a new formulation in a combined rat model of OP and OA. The formulation (BIS076) contains Vitamin D3, Hydroxyapatite as a source of calcium and a natural extract from porcine cartilage. The latter is rich in bioactive substances due to the mild conditions used in the manufacturing process.
Methods: OP was induced by ovariectomy in female Wistar rats (180-200g body weight, n= 15 rats/group) (week 0) and 2 weeks after (week 2) OA was induced by Anterior Cruciate Ligament Transection (ACLT). All surgical procedures were carried out under deep anaesthesia with isofluorane (1.5 minimum alveolar concentration) which was followed by the subcutaneous injection of butorphanol (2mg/kg). Animals were maintained at a temperature of 21±2oC, with a 12 hour light/dark cycle and with free access to food and tap water. BIS076 was administered daily (oral gavage) at two doses from week 0 until week 12 after ovariectomy. The low dose was 163.5 mg/kg/day and the high dose 245 mg/kg/day which correspond approximately to 1400 mg/day and 2100 mg/day in humans. A Control Group and an ovariectomized + ACLT Group (Vehicle Group) were also included. After week 12, animals were sacrificed. For the assessment of OA, histology was performed and cartilage degeneration was evaluated by means of the OARSI score. Synovitis degree was estimated according to the score proposed by Krenn et al. Bone microarchitecture and density were assessed by microCT.
Results: The preparation BIS076 has been shown to induce, at the 2 doses tested, a significant reduction (approximately 50%) of the cartilage degradation according to the OARSI score. Synovial inflammation was strongly reduced as well. In addition, microCT revealed that BIS076 treatment exerted a positive effect in bone structure, especially at the high dose: Significant increase in bone volume ($p<0.05$), bone surface density ($p<0.01$), trabecular number ($p<0.01$) and significant reduction in the trabecular bone pattern factor ($p<0.01$) compared to the Vehicle Group.
Conclusions: Our data demonstrate that treatment with BIS076 could be an effective strategy to control the progression of experimental Osteoarthritis and Osteoporosis. This approach holds promise for the development of improved therapies targeting these chronic and disabling diseases.

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THE ANTI-INFLAMMATORY CAPACITY OF ROSE-HIP IS STRONGLY DEPENDENT ON THE SEEDS - A COMPARISON OF ANIMAL AND HUMAN STUDIES

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Purpose: A standardized preparation from selected subspecies of rose-hip, developed and produced on Langeland, Denmark, trade name Hyben-Vital®, has drawn increasing attention as an anti-inflammatory agent and a meta-analysis indicate that the remedy can alleviate symptoms of osteoarthritis. The powder consists of an equal amount of shells and seeds. The purpose of this study was to evaluate if the anti-inflammatory capacity is dependent on seeds.
Methods: The clinical studies were double-blinded, placebo-controlled and randomized and lasted from 3 to 6 month. Blood samples for laboratory analysis were drawn initially and after at least 3 month treatment. As the in vivo inflammatory marker, C-reactive protein (CRP) is not well established in animal models we used, chemotaxis, a modified Boyden chamber technique, to measure migration of polymorphnucleated cells (PMN`s) to the inflammatory sites. Inhibition of migration indicates anti-inflammatory property. The methodology is well established and results in comparable data when testing different animal species including horses and dogs. In studies on humans we measured CRP, using normal laboratory routine, at the initial level and again after 3 to 6 month of treatment. In the animal study, two different preparations of Rose-hip powder were used: One version of powder